12.0 510(k) Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. **Name of Manufacturer, Contact Person and Date Summary Prepared:**

Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673
Phone: 949-940-7260
FAX: 949-940-7313
Contact Person: Jimmy Wong, Manager of Clinical and Technical Affairs
Date Prepared: July 22, 2002

2. **Device Name:**

Trade/Proprietary Name:	Nichols Advantage® QuiCk-IntraOperative Bio-Intact PTH (1-84)
Common Name:	Intraoperative PTH Immunoassay
Classification Name:	Parathyroid hormone test system

3. **Classification:** Class II
Regulation Number: 862.1545
Product Code: CEW, Clinical Chemistry

4. **Predicate Device:** Nichols Advantage Bio-Intact PTH (1-84)

5. **Device Description:**
The Nichols Advantage QuiCk-IntraOperative Bio-Intact PTH (1-84) assay contains sufficient reagents for 26 tests. The assay is a two-site chemiluminometric assay specific for hPTH 1-84.

6. **Intended Use:**
The Nichols Advantage QuiCk-IntraOperative Bio-Intact PTH (1-84) is intended for use with the Nichols Advantage Specialty System to measure parathyroid hormone in EDTA plasma and human serum. This procedure is recommended for rapid intraoperative measurement of Intact PTH 1-84 using EDTA plasma or human serum. The reagent cartridge is designed for single use only.

7. **Comparison to Predicate Device:**
The Nichols Advantage QuiCk-IntraOperative Bio-Intact PTH (1-84) (Y) was compared to the Nichols Advantage Bio-Intact PTH (1-84) assay (X) previously cleared by the FDA. One hundred thirty (130) remnant serum samples in which the clinical diagnosis were unknown were assayed in duplicate by both methods following the manufacturers' directions. The range observed with method "X" was 10.8 to 773 pg/mL; range for method "Y" was 12.3 to 792 pg/mL. Passing Bablok regression analysis of these data yielded an equation of Y = 1.00X - 1.1 (95% confidence intervals for slope and intercept were 0.97 to 1.03, and -2.9 to +0.8 respectively). Deming regression analysis of these data yielded an equation of Y = 0.985X - 0.3 (95% confidence intervals for slope and intercept were 0.96 to 1.01, and -4.6 to +3.9 respectively). Pearson's correlation coefficient (r) of the paired data was 0.99.

8. **Similarities:**

- Specimen type is identical for both methods.
- Both assays use hPTH 1-84 as standards, and both report values using the same units: pg/mL.

- Both assays use the same immunometric approach to measure PTH, and both assay methods use the same antibody pair for capture and detection of the hormone.

9. Differences:

The following differences pertain to differences in immunoassay technology and do not affect the intended uses of the PTH assay.

Feature	QuiCk-IntraOperative PTH	Bio-Intact PTH (1-84)
Sample Size:	250 uL EDTA plasma or serum	150 uL serum or plasma
Incubation steps and temperature:	2 minutes @ 37°C	30 minutes @ 37°C
Analytical sensitivity Functional sensitivity	5 pg/mL 12 pg/mL	1.5 pg/mL 4 pg/mL

10. Comparison of Performance Characteristics

Feature	QuiCk-IntraOperative PTH	Bio-Intact PTH (1-84)
Within-Run Precision (%CV)	3.9-16.1%	2.2-3.6%
Total Precision (%CV)	5.8-22.6%	5.6-8.3%
Recovery	94-117%	94-103%
Linearity	99-111%	92-109%

Conclusions: These data, which were provided to FDA, demonstrate safety and effectiveness of the Nichols Advantage QuiCk-IntraOperative Bio-Intact PTH (1-84) for its intended in vitro diagnostic use. Furthermore, based on performance characteristics, the Nichols Advantage QuiCk-IntraOperative Bio-Intact PTH (1-84) assay is substantially equivalent to the predicate method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 0 9 2002

Mr. Jimmy Wong
Manager, Clinical and Technical Affairs
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673

Re: k022472
Trade/Device Name: Nichols Advantage QuiCk-IntraOperative™ Bio-Intact PTH (1-84)
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW
Dated: July 24, 2002
Received: July 26, 2002

Dear Mr. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications For Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number: K022472

Device Name: Nichols Advantage QuiCk-IntraOperative™ Bio-Intact PTH (1-84)

Indications for Use Statement: The Nichols Advantage QuiCk-IntraOperative™ Bio-Intact PTH (1-84) is intended for use with the Nichols Advantage® Specialty System to measure parathyroid hormone in EDTA plasma and human serum. This procedure is recommended for rapid intraoperative measurement of Intact PTH 1-84 using EDTA plasma or human serum. The reagent cartridge is designed for single use only.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

X **Prescription Use** (Per 21 CFR 801.109) Or **Over –The-Counter Use** (Optional Format 1-2-96)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022472